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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,489	05/25/2000	Ray W. Wood	029318/0596	7761

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SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/577,489

Applicant(s)

WOOD ET AL.

Examiner

Sabiha N. Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 28-40, 42-45 and 47-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 28-40, 42-45 and 47-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Final Office Action

Acknowledgement is made of the amendments and response filed on 2/4/04. Claims 28-40, 42-45, and 47-59 are pending. No claim is allowed. Double patenting rejection is withdrawn, because a terminal disclaimer has been filed and accepted. Other rejections are maintained for the same reasons as set forth in our previous office action.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The arguments filed on 2/04/04 were fully considered, but are not found persuasive. Examiner disagrees that, at the time of invention, "it was not known that nanoparticulate formulations could be incorporated into aerosol formulations, much less any that could be delivered to a mammal's lung as discovered and claimed by present invention". Furthermore, Examiner respectfully disagrees that, at the time when the invention was made, "the claimed invention satisfies a need in the art for aerosol compositions that can deliver a poorly soluble active agent to the lungs". This is Examiner's position that "aerosol compositions" were known at the time of invention. A reference of JAMES is enclosed where aerosols were used in 1989. A rejection is being made on that reference, which teaches the aerosol, far earlier than the invention was made.

For the reasons cited above the claimed invention *is* described and suggested in the cited prior art and would have been obvious to one skilled in the art.

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This Application is a CIP of 08/394103 filed on Feb. 24, 1995, now abandoned. The priority not granted because the subject matter in this application is different from the subject matter in 08/394103.

The Examiner requests the Applicants to show the support in 08/394103 and as well as in present application for the presently claimed invention (claims 10-40, 42-45, and 47-59). The comparison shown in remarks for support is confusing. It is unclear the reference is being made for the present application or 08/394,103.

Even though the priority issue has not been resolved yet, the James reference (1989) is considered to be sufficient to show that present invention was obvious at the time of invention was made.

Rejection of Claims 28-40, 42-45, and 47-59 Under 35 U.S.C. 112, (1) is withdrawn because claims are amended.

Claim Rejections - 35 USC § 103

1st Rejection

Claims 28-40, 42-45, and 47-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over the AIDS Treatment Network Article "Aerosol Pentamidine Gets "Treatment IND" Approval" ("JAMES, John S.") and US Patent No. 5145684 ("Liversidge et al."). All of the references cited teach a composition that embraces Applicant's claimed invention.

The JAMES, John S. reference teaches the use of aerosol pentamidine for prevention of pneumocystis, under the "treatment IND" rules for providing early access to new treatments for life- threatening conditions. It goes on to state, "LyphoMed has agreed to continue trials of

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aerosol pentamidine for 24 months, even after full FDA approval, so some patients will receive free treatment through this study.”

Liversidge et al. teaches that commercial air jet milling techniques provide particles ranging in average particle size from as low as 1,000 to 50,000 nm (1 to 50 microns). The reference also teaches crystalline drug particle having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective particle size of less than 400 nm. See the entire document, especially lines 47-50 in col. 1, claims, and examples.

Instant claims differ from Liversidge et al. in that Liversidge et al. does not have aerosols. However, the JAMES, John S. reference teaches aerosols for pentamidine, which were used at the same time as injections. The reference also teaches “aerosol pentamidine was already widespread use before this treatment IND. Several different doses had been used.”

It would have been obvious skilled in the art at the time of invention was made to prepare an aerosol composition to use for the treatment of respiratory diseases because Liversidge et al. teaches the average particle size, surface modifier, and all other limitations of the presently claimed invention EXCEPT for aerosols.

The JAMES, John S. reference teaches aerosol pentamidine compositions for the prevention of pneumocystis, a microscopic fungus that infects the lungs of mammals. The use of aerosols was known in 1989. Therefore, in view of the teaching of Liversidge et al. and JAMES, John S., the present invention is considered obvious.

In the light of the forgoing discussion, the Examiner’s ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

2nd Rejection

Claims 28-40, 42-45, and 47-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5747001 ("Wiedmann et al."), US 6264922 ("Wood et al."), and US 5145684 ("Liversidge et al."). All of the references cited teach a composition that embraces Applicant's claimed invention.

See lines 20-67, col. 2, in Wiedmann et al., where an aerosol comprising nanoparticles of beclomethazone dipropionate having surface modifier on the surface, for administering to the respiratory system is taught. See also lines 5-67, col. 3 and lines 1-67 in col. 4 where surface modifiers are listed.

Weidmann et al. teaches the particle size less than 400 nm, whereas instant invention claims less than 1000 nm. See entire document, especially Tables I-III in col. 14, claims, and examples.

Liversidge et al. teaches that commercial airjet milling techniques provide particles ranging in average particle size from as low as 1,000 to 50,000 nm (1 to 50 microns). The reference also teaches crystalline drug particle having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective particle size of less than 400 nm. See the entire document, especially lines 47-50 in col. 1, claims, and examples.

Wood et al.'s claim 24 teaches a method of treating a mammal in need comprising delivering nanoparticles to the lungs of the mammal, wherein said method comprises the steps of:

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(a) forming a nebulized aerosol of an dispersion of liquid droplets, wherein the aerosol is useful for delivery of the nanoparticles to the lungs of a mammal, wherein:

- (i) The liquid droplets have a particle size of less than about ten microns in diameter;
- (ii) the liquid droplets consist essentially of a liquid, a crystalline therapeutic agent, and at least one surface modifier; and
- (iii) The aerosol is useful for delivery of the nanoparticles to the lungs of a mammal;

wherein said nanoparticles consist essentially of:

(1) Crystalline particles of a therapeutic agent which is poorly soluble in said liquid, wherein the crystalline agent particles have an effective average particle size of less than about 1000 nm; and

(2) About 0.1 to 90% (w/w) of at least one surface modifier, based upon the combined weight of the surface modifier and the therapeutic agent, adsorbed on the surface of the crystalline therapeutic agent particles; and

(b) Administering said aerosol to the lungs of said mammal.

The prior art cited above teach all the limitations of the claimed invention.

Instant invention is generically taught by the prior art.

It would have been obvious to one skilled in the art to prepare additional beneficial composition for the delivery and/or treatment of respiratory system by using the composition of the crystalline drug such as steroid containing particles of size less than 1000 nm because surface modifiers, droplets and crystalline particles of less than 1000 nm are taught by the prior art cited above. Instant invention would have been obvious at the time of invention because surface

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modifiers are used, the sizes of the nanoparticles are less than 1000 nm, and aerosols are droplets.

In the absence of a showing of criticality, of unobviousness or unexpected results over the prior art, the instant invention is considered obvious over the prior art for the reasons cited above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Communication


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5/31/04


SABIHA QAZI, PH.D
PRIMARY EXAMINER